



CERTIFIED
RETURN RECEIPT REQUESTED

Food and Drug Administ
Detroit District
1560 East Jefferson Ave
Detroit, MI 48207
Telephone: 313-226-6260


WARNING LETTER
97-DT-04

November 1, 1996

Ms. Beverly Lawson, Owner
Grandma Morrison's
P.O. Box 27
Bellmore, IN 47830

Dear Ms. Lawson:

An inspection was made of your acidified low acid canning plant on September 23 & 30, 1996 by Investigator Brian P. Hendrickson and Inspector Beverley A. Phillips. The inspection revealed significant deviations from the regulations set forth in Title 21, Code of Federal Regulations, Part 114, Acidified Foods (21 CFR 114). These deviations cause your products to be adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug and Cosmetic Act (the Act). The deviations found during the inspection were:

1. The two pH meters used to measure the acidity of your products had not been calibrated regularly to determine their ability to function adequately and there were no calibration records on file.
2. The red pH meter did not function adequately during a calibration test on 9/23 and the black pH meter did not function adequately either.
3. The red pH meter's electrodes were handled in a manner where they could become fouled or damaged in that the storage water was not changed regularly and the electrodes were immersed in hot cover brine to measure the pH.
4. The test method did not comply with the regulation in that the equilibrium pH of the finished product was not determined and the hot cover brine was tested for pH at  degrees C rather than at the temperature specified in the regulation.
5. Company personnel were not familiar with the operating and maintenance procedures for the pH meters and there were no written instructions available for the calibration and maintenance of the meters.
6. The scheduled processes for acidified low acid canned foods have not been established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

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7. Operating personnel are not under the supervision of a person who has attended and satisfactorily completed an approved school for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification.

These deviations were listed on an Inspectional Observations list (FDA-483) which was given to you at the conclusion of the inspection. The FDA-483 is not intended to be an all inclusive list of deviations at your firm. It is your responsibility to assure that all of your firm's products comply with the requirements of the Act and its implementing regulations. We note that by the conclusion of the inspection, you had taken effective steps to correct the deficiencies related to the use, calibration, care and maintenance of the pH meter.

You should take prompt action to correct these deviations and to prevent their recurrence. Failure to promptly correct them may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which corrections will be implemented.

Your response should be directed to this office to the attention of Mr. John E. Klemmer, Compliance Officer.

Sincerely yours,

Brenda J. Holman
Brenda J. Holman
District Director
Detroit District